

Commonwealth of Virginia  
Department of General Services  
Division of Consolidated Laboratory Services  
Richmond, Virginia

**Ch 46 Quality Manual Completeness Checklist for New Applicants- TNI 2009**

**Laboratory Name** \_\_\_\_\_ **EPA Lab ID** \_\_\_\_\_

*Please indicate by section number and/or page number, where the following elements are found in the submitted*

*Laboratory Quality Manual. **SUBMIT DOCUMENTATION AS NOTED.***

Mandatory Quality Elements & 2009 TNI V1M2 References	Laboratory Reference	Document Compliant			Comments and Corrective Actions  (DCLS USE ONLY)
		Y	N	N/A	
<b>4.2.8.3 The quality manual shall contain:</b>					
4.2.8.3 (a) Document title					
4.2.8.3 (b) Laboratory's full name and address					
4.2.8.3 (c) Name, address (if different from above), and telephone number of individual(s) responsible for the laboratory					
4.2.8.3 (d) Identification of all major organizational units which are to be covered by this quality manual and the effective date of the version					
4.2.8.3 (e) Identification of the laboratory's approved signatories					
4.2.8.3 (f) The signed and dated concurrence (with appropriate names and titles), of all responsible parties including the quality manager(s), technical manager(s), and the agent who is charge of all laboratory activities, such as the laboratory director or laboratory manager					
4.2.8.3 (g) The objectives of the quality system and contain or reference the laboratory's policies and procedures					
4.2.8.3 (h) The laboratory's official quality policy statement, which shall include quality system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard					
4.2.8.3 (i) A table of contents, and applicable lists of references, glossaries and appendices					
<b>4.2.8.4 The quality manual shall contain or reference:</b>					
4.2.8.4 (a) All maintenance, calibration and verification procedures used by the laboratory in conducting tests <b>SUBMIT AN EXAMPLE OF THE LABORATORY'S CALIBRATION DATA AND ASSOCIATED QUALITY CONTROL FOR TWO ANALYSIS METHODS.</b>					DATA REVIEW REQUIRED.
4.2.8.4 (b) Major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests					
4.2.8.4 (c) Verification practices, which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes					
4.2.8.4 (d) Procedures for reporting analytical results					
4.2.8.4 (e) The organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts					
4.2.8.4 (f) Procedures to ensure that all records required under this Standard are retained, as well as procedures for control and maintenance of documentation through a document control system that					

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		Y	N	N/A	
ensures that all standard operating procedures (SOPs), manuals, or documents clearly indicate the time period during which the procedure or document was in force					
4.2.8.4 (g) Job descriptions of key staff and reference to the job descriptions of other laboratory staff					
4.2.8.4 (h) procedures for achieving traceability of measurements (This requirement refers to documentation linking a measurement to the specific lot numbers of equipment, standards, reagents, and media used to achieve the measurement.) <b>SUBMIT SAMPLES FROM TWO DIFFERENT ANALYSES DEMONSTRATING DOCUMENTATION OF TRACEABILITY OF MEASUREMENTS TO THE SPECIFIC EQUIPMENT, STANDARDS, REAGENTS, AND MEDIA USED.</b>					DATA REVIEW REQUIRED.
4.2.8.4 (i) A list of all methods under which the laboratory performs its accredited testing <b>SUBMIT TWO STANDARD OPERATING PROCEDURES FOR REQUESTED METHODS.</b>					DATA REVIEW REQUIRED.
4.2.8.4 (j) Procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work					
4.2.8.4 (k) procedures for handling samples <b>SUBMIT AN EXAMPLE PAGE FROM THE LABORATORY'S SAMPLE RECEIVING LOG.</b>					DATA REVIEW REQUIRED.
4.2.8.4 (l) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur <b>SUBMIT AN EXAMPLE OF DOCUMENTATION FOR CORRECTIVE ACTION TAKEN FOR A FAILED PT OR OTHER POLICY DEPARTURE WITHIN THE LAST 6 MONTHS.</b>					DATA REVIEW REQUIRED.
4.2.8.4 (m) policy for permitting departures from documented policies and procedures or from standard specifications					
4.2.8.4 (n) procedures for dealing with complaints					
4.2.8.4 (o) procedures for protecting client confidentiality (including national security concerns), and proprietary rights					
4.2.8.4 (p) procedures for audits and data review					
4.2.8.4 (q) procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training <b>SUBMIT AN ANALYST'S COMPLETE TRAINING RECORD, INCLUDING SUPPORTIVE DEMONSTRATION OF CAPABILITY DOCUMENTATION.</b>					DATA REVIEW REQUIRED.
4.2.8.4 (r) policy addressing the use of unique electronic signatures, where applicable					
<b>DCLS Checklist Review</b> <b>Initials/Date:</b> _____					

Return completed checklist to DCLS with Quality Manual